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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,477	04/13/2001	Anthony A. Fossa	PC10148AGPR	2582

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/834,477	Applicant(s) FOSSA, ANTHONY A.	
	Examin r David Lukton	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The following abbreviations are used hereinbelow:

"CRFA" = corticotropin releasing factor antagonist;

"GHS" = growth hormone secretagogue;

"GH" = growth hormone

*

A restriction is imposed, as set forth below. First, however, the following subgenera are defined:

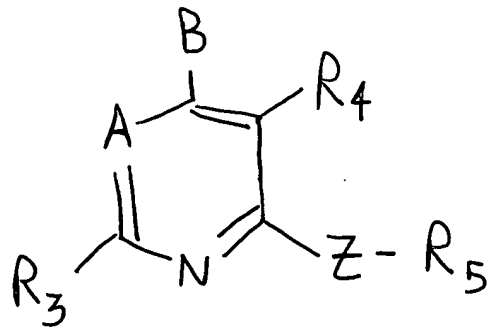
G1: the CRFA is limited to those recited in claims 2-6 and 8, with the proviso that G5 is excluded;

G2: the CRFA is limited to those recited in claims 7 and 9

G3: the CRFA is limited to those recited in claim 10;

G4: the CRFA is limited to those recited in claims 11-12;

G5: the CRFA is limited to the following, wherein the substituent variables are as defined in claim 4:



G6: the GHS is limited to that which is defined in claim 15.

*

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claim 1, wherein the CRFA and GHS can be whatever claim 1 permits, with the proviso that subgenera G1 - G6 are excluded.

2. Claim 15, wherein the GHS is limited to G6, and the CRFA can be whatever claim 1 permits, with the proviso that subgenera G1 - G5 are excluded.

3. Claims 2-6 and 8, wherein the GHS is limited to G6, and the CRFA is limited to G1.

4. Claims 7 and 9, wherein the GHS is limited to G6, and the CRFA is limited to G2.

5. Claim 10, wherein the GHS is limited to G6, and the CRFA is limited to G3.

6. Claims 11-12, wherein the GHS is limited to G6, and the CRFA is limited to G4.

7. Claim 4, wherein the GHS is limited to G6, and the CRFA is limited to G5.

8. Claims 23-28, drawn to methods of using a CRFA and a GHS or GH.

9. Claims 29, 32, 34, 35 drawn to a kit.

None of claims 13, 14, 16-22 , 30, 31 or 33 is grouped. In the event that one of Groups 1-7 is elected, claims 13, 14, 16-22 , 30, 31 and 33 will be joined with that group.

The claimed inventions are distinct.

Claim 1 is of infinite size. In addition, there exists a vast "sea" of literature of

corticotropin releasing factor antagonists and growth hormone secretagogues. In addition, there exist numerous references which disclose that certain compounds exert certain effects on a given biochemical process "X", and at the same time, secondary references which disclose that if one can modulate biochemical process "X", one can succeed in inhibiting the release of corticotropin releasing factor. To search for, and reject over, each of the several thousand references that are potentially applicable would certainly impose an undue burden. The various inventions identified above as Groups 1-7 are distinct from one another. They each define different genera of corticotropin releasing factor antagonists and growth hormone secretagogues.

Inventions 1-7 and 8 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the event that one of Groups 1-8 is elected, and claims therein found allowable, the method-of-use claims will be rejoined therewith, subject to the same limitations on the structures of the "CRFA" and "GHS". Similarly, In the event that one of Groups 1-8 is elected, and claims therein found allowable, the "kit" claims will be rejoined therewith, subject to the same limitations on the structures of the "CRFA" and "GHS".

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect two disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The first specie is a specific corticotropin releasing factor antagonist with a fully defined structure. The second specie is either of the following: (a) a specific growth hormone secretagogue or (b) a specific growth hormone peptide that is identified by the species of animal that produces it, or by a specific amino acid sequence.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600